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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/496,893	02/02/2000	Stephen J. Brown	HERO-1-1089	6810

25315 7590 06/04/2003

BLACK LOWE & GRAHAM
816 SECOND AVE.
SEATTLE, WA 98104

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/04/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/496,893

Applicant(s)

Brown

Examiner

Ardin Marschel

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 8/27/01 and 11/8/01

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 30-36 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 30-36 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) ☐ Other: _____

An amendment, filed 11/8/01, to the instant claims with arguments crossed in the mail with the previous office action, mailed 12/3/01. Regrettably, an office action which takes this amendment, filed 11/8/01, has been inadvertently slow in being prepared. This office action now responds to said 11/8/01 amendment and continues prosecution of this application.

Applicant's arguments, filed 8/27/01 and 11/18/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

PRIORITY

If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. It is noted that such a reference appears in the first paragraph of the instant specification, but does not contain a citation to parent application serial number 09/041,809. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent

application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

TITLE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The pending claims are directed to methods for identifying a disease-influencing gene whereas the present title lacks any indication of this method and thus is confusingly different from the claimed invention subject matter.

ABSTRACT

The Abstract of the Disclosure is objected to because it exceeds 150 words. A shortened abstract of a single paragraph on its own separate sheet of paper is required. Correction is required. See M.P.E.P. § 608.01(b).

NEW MATTER

Claims 30-36 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Consideration of the newly submitted claims reveals that they contain NEW MATTER which has not been found in the instant disclosure as filed. The following newly submitted claims

limitations are NEW MATTER, listed and further explained as follows:

- 1) environmental or behavioral risk factors (claim 30, lines 3-7 etc.) - It is acknowledged that environmental and behavioral information is acquired but there is no specific written description of these as being "risk" factors per se.
- 2) selecting of a disease where an environmental, behavior risk factor is physiologically associated with a disease (claim 30, lines 3-4) - It is acknowledged that physiological information including environmental and behavioral information is acquired but a disclosure of the association of these elements of information for disease selection has not been found as filed.
- 3) presenting remote apparatus/user interface to disease and non-disease populations (claim 30, line 8, etc.) - It is acknowledged that various diseased individuals are described as filed as being presented with the remote apparatus/user interface such as individuals with various disease severities as on page 30, lines 25-33; page 31, lines 16-22; and page 31, lines 20-33, but not inclusive of non-disease populations.
- 4) target-based genotype testing (claim 30, line 21, etc.) - It is acknowledged that "gene sequences" (plural) are analyzed as disclosed in the last 6 lines of the abstract and that genomes of all individuals are sequenced as described in the instant disclosure at page 12, lines 4-5; page 12, lines 12-13; page 12,

lines 30-31, etc.; but that there is no written basis for "target-based genotype" testing as filed.

5) disease vs. non-disease databases utilized for the identification of a target gene (claim 30, last 2 lines) - It is acknowledged that disease population databases are utilized as described as filed for gene identification but not disease vs. non-disease databases practice.

6) risk factors being diet, lifestyle, geographical location, and disease progression (claim 31) - It is acknowledged that information regarding diet etc. is disclosed as being gathered as filed but not that these are risk factors per se.

7) target-based genotype testing directed to positional cloning, functional cloning, and comparative gene expression analysis (claim 32) - It is acknowledged that positional cloning etc. is disclosed as filed but not that these testing methods are directed to target-based genotype testing regarding the instant invention.

8) cDNA sequencing of mRNA (claim 33) - No cDNA sequencing from mRNA has been found as filed regarding written basis.

9) gene expression analysis configured to determine environmental factor contribution to disease development (claim 34) - It is acknowledged that environmental information is acquired but that disease development per se has not been found as filed as being analyzed via gene expression analysis to

determine its contribution to said disease development.

10) continuously receiving data signals over a long period of time (claims 34 and 35) - It is acknowledged that data collection over a long period of time is disclosed as filed but not "continually" over this period.

11) positional cloning configured for determining environmental factor contribution to developing disease (claim 35) - The direct configuration of positional cloning to connect environmental contribution to disease development has not been found as filed.

No claim is allowed.

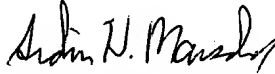
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 2, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER